UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,125	01/05/2001	Daniel Gelber	XMP 2032	3248

30868 7590 11/25/2003

KRAMER & AMADO, P.C.
2001 JEFFERSON DAVIS HWY
SUITE 1101
ARLINGTON, VA 22202

EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	5

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/754,125	GELBER ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12-20,25,26,31,53-63,67-75,80,81 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 9-11,21-24,27-30,32-52,64-66,76-79,82-85 and 87-110.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: an immune booster

Subspecies 1: zinc or salts thereof

Subspecies 2: herbs of the genus Echinacea

Subspecies 3: herbs of the genus Sambucus

Subspecies 4: herbs of the genus Goldenseal

Species 2: an anti-inflammatory nutraceutical

Subspecies 1: a bioflavonoid or an herbal extract containing a bioflavonoid

Subspecies 2: curcumin or an herbal extract containing curcumin

Subspecies 3: stinging nettle or extracts thereof

Subspecies 4: bromelain

Species 3: an antioxidant

Subspecies 1: a bioflavonoid or an herbal extract containing a bioflavonoid

Subspecies 2: ascorbic acid or salts thereof

Subspecies 3: garlic or extracts thereof

Subspecies 4: green tea or extracts thereof

Subspecies 5: herbs of the genus Astragalus

Species 4: a liver protectant

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and within that species, a single subspecies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-11 and 56-66 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Arlir Amato on February 24, 2003 a provisional election was made with traverse to prosecute the invention of the species of immune booster, specifically herbs of the genus Sambucus, claims 1-8, 12-20, 25-26, 31, 53-63, 67-75, 80-81 and 86. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-11, 21-24, 27-30, 32, 33-52, 64-66, 76-79, 82-85, 87, and 88-110 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

Claims 3, 13, 54, 55, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group that recites "the group consisting of acetaminophen, non-steroidal anti-inflammatory drugs (NSAID's), and mixtures thereof" is improper because

the members of the group are not mutually exclusive. Acetaminophen is considered to fall within the category of NSAIDs.

There is no antecedent basis for the term "elderberry" in any claim from which claims 54 and 55.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12-16, 18-19, 25, 31, 53, 56-63, 67-71, 73-74, 80 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by RO 113712.

The reference discloses a composition for treatment of a flu-preventing medicine containing aspirin (an NSAID), paracetamol (acetaminophen), an extract of Sambucus (immune booster), ascorbic acid (an antioxidant), phenylpropanolamine (a decongestant) and chlorpheniramine (an anti-histamine). Broadest reasonable interpretation of the term "NSAID" in the art is deemed to include aspirin. Therefore, the claims are anticipated by the disclosure of the prior art reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17, 20, 26, 54-55, 75, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over RO 113712 combined with JP 10298088, Suzuki et al., Muriel et al., Nagai et al., and Campos et al.

RO 113712 teaches a flu-preventing composition that contains aspirin (an NSAID), paracetamol (acetaminophen), an extract of Sambucus (immune booster), ascorbic acid (an antioxidant), phenylpropanolamine (a decongestant) and chlorpheniramine (an anti-histamine).

JP 10298088 teaches a cold-treating composition which contains an antipyretic analgesic which is disclosed as being an NSAID such as acetaminophen combined with Echinacea and other medications such as bromelain, ascorbic acid, and antihistamines.

Suzuki et al. teach a powdery composition for treatment of the nasal mucosa and teach all of the conventional medications that are used to treat the nasal mucosa in col. 4.

Both Muriel et al. and Campos et al. teach that silymarin (milk thistle) can protect against acetaminophen hepatotoxicity. Nagai et al. teach that plant bioflavonoids are active against influenza virus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select conventional NSAIDs, as well as conventional antihistamines, as well as conventional decongestants, and combine them with nutraceuticals such as Sambucus, ascorbic acid, bromelain, bioflavonoids and milk thistle for the treatment of colds and flu, as these components have been used in various combinations for the same purpose in the prior art. The inclusion of milk thistle is motivated by the potential for hepatotoxicity of acetaminophen thereby providing protection against said hepatotoxicity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jean C. Witz
Primary Examiner
Art Unit 1651